

**Detailed Action**

Status of claims. Claims 401, 411, 414, 416, 419, 422-424, 464, 465, 469-471 and 478-480 are currently pending. Claims 401 and 411 have been amended by Applicants' amendment filed on 11-12-2010.

The examiner contacted Applicants' representative, Matthew Pavao on February 9, 2011, to discuss an amendment to the pending claims filed on 11-12-2010 to cancel product claims 411, 465 and 478-480 and to set forth the pending methods claims in condition for allowance. Authorization for the examiner's amendment was given in a telephone interview with Matthew Pavao on Feb 10, 2011.

The examiner acknowledges receiving a Declaration under 37 C.F.R. § 1.132 signed by Dr. Toni Peled filed on 11-12-2010.

With respect to the proposed claims, an examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

**In the claims,**

Claims 411, 465 and 478-480 have been cancelled.

**Reasons for allowance**

The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or suggest of

A method of expanding a population of CD34+ hematopoietic stem cells ex-vivo, while at the same time, inhibiting differentiation of the stem cells ex-vivo, the method comprising:

(a) culturing said CD34+ hematopoietic stem cells ex-vivo under conditions allowing for cell proliferation, said conditions which comprise providing nutrients, serum and a combination of cytokines including each of stem cell factor, thrombopoietin, FLT3 ligand, and IL-6 and optionally IL-3 and,

(b) in the same culture medium providing nicotinamide in an amount between 1.0 mM to 10 mM,

wherein culturing said cells [are cultured] for a culture period of three weeks results in expanding the population of CD34+ hematopoietic stem cells while inhibiting differentiation of said CD34+ hematopoietic stem cells ex-vivo to produce an expanded CD34+ hematopoietic stem cell population with an increased proportion of CD34+/Lin- and CD34+/CD38- cells in the expanded culture as compared to CD34+ cells cultured in the presence of cytokines and nutrients without exogenously added nicotinamide.

***Withdrawn rejections in response to Applicants' arguments or amendments***

**Claim Rejections - 35 USC § 103**

In view of Applicants' amendment of claim 401, rejection of claims 401, 414, 416, 419, 422-424, 464 and 469-471 under 35 U.S.C. 103(a) as being unpatentable over Brown R (US Publication No. 2002/0159984, Date of Publication October 31, 2002) over Block et al., (US Patent 6,413,772, Date of Patent July 2, 2002) has been withdrawn.

Though Brown R. exemplifies cultures of bone marrow CD34+ enriched populations showing CD34+/CD38- cells with significant expansion at days 3, 7 and 14, the combination of Brown and Block fails to teach or suggest that nicotinamide concentrations of 1.0 mM to 10 mM in serum and the claimed combination of cytokines increases proportions of CD34+/lin- and

CD34+/CD38- in CD34+ cells cultured for a period of three weeks, which requires culturing for three weeks or beyond three weeks.

### **Conclusion**

Claims 401, 414, 416, 419, 422-424, 464 and 469-471 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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